

What is claimed is:

1. An implant that supplements, repairs, or replaces a native heart valve leaflet or leaflets comprising

5 a scaffold sized and configured to rest adjacent all or a portion of a native heart valve annulus, at least a portion of the scaffold defining a pseudo-annulus,

a neoleaflet element coupled to the scaffold
10 within pseudo-annulus and being sized and shaped to occupy the space of at least a portion of one native heart valve leaflet to provide a one-way valve function that, in response to a first pressure condition, assumes a valve opened condition within the pseudo-annulus and,
15 in response to a second pressure condition, assumes a valve closed condition within the pseudo-annulus, and

spaced-apart struts appended to the scaffold and being sized and configured to contact tissue near or within the heart valve annulus to brace the scaffold
20 against migration within the annulus during the one-way valve function.

2. An implant according to claim 1 wherein the scaffold comprises a wire-form structure.

25 3. An implant according to claim 1 wherein at least one of the struts comprises a wire-form structure.

4. An implant according to claim 1 wherein the scaffold and the struts each
30 comprises a wire-form structure.

5. An implant according to claim 1 wherein the neoleaflet element includes a bridge appended to the scaffold.

35 6. An implant according to claim 5 wherein the neoleaflet element includes a

material covering the bridge.

7. An implant according to claim 5
wherein the bridge is a wire-form structure.
8. An implant according to claim 1
5 wherein the neoleaflet element includes a
duckbill valve within the psuedo-annulus.
9. An implant according to claim 1
wherein the neoleaflet element includes a
membrane within the pseudo-annulus.
10. An implant according to claim 1
10 wherein the neoleaflet element is sized and
configured to coapt with a native leaflet when in the
valve closed condition.
11. An implant according to claim 1
15 wherein the scaffold, neoleaflet element, and
the struts are collapsible for placement within a
catheter.
12. An implant according to claim 1
wherein at least one of the struts carries a
20 structure sized and configured to increase a surface area
of contact with tissue at, above, or below the annulus.
13. An implant according to claim 1
further including at least one structure
25 appended to the scaffold and being sized and configured
to contact tissue at, above, or below the heart valve
annulus to stabilize the scaffold.
14. An implant according to claim 1
wherein the scaffold, neoleaflet element, and
struts include materials and shapes to provide a spring-
30 like bias for compliance with anatomy near or within the
heart valve annulus.
15. An implant according to claim 1
wherein the struts apply tension to tissue.
16. An implant according to claim 1
35 wherein the struts apply tension to tissue to

- 25 -

reshape the heart valve annulus.

17. An implant according to claim 1

wherein the struts apply tension to separate tissue along an axis of the heart valve annulus.

5 18. An implant according to claim 1

further including a second heart valve treatment element appended to the scaffold to affect a heart valve function.

19. An implant according to claim 18

10 wherein the second heart valve treatment element includes means for reshaping the heart valve annulus for leaflet coaptation.

20. An implant according to claim 18

15 wherein the second heart valve treatment element includes means for stretching leaflet commissures for leaflet coaptation.

21. A method for supplementing, repairing, or replacing a native heart valve leaflet or leaflets comprising the steps of

20 introducing an implant as defined in claim 1 into a heart, and

providing a one-way valve function that, in response to a first pressure condition, assumes a valve opened condition and, in response to second pressure condition, assumes a valve closed condition by locating the scaffold as defined in claim 1 adjacent all or a portion of a native heart valve annulus to define a pseudo-annulus, with the neoleaflet element as defined in claim 1 occupying the space of at least a portion of one native heart valve leaflet to provide the one-way valve function, and with the spaced-apart struts as defined in claim 1 contacting tissue near or within the heart valve annulus to brace the scaffold against migration within the annulus during the one-way valve function.

35 22. A method according to claim 21

wherein the introducing step comprises using
an open heart surgical procedure.

23. A method according to claim 21
wherein the introducing step comprises using a
5 surgical procedure in which the implant is carried within
a catheter.

24. A method according to claim 21
wherein the introducing step comprises using
an intravascular surgical procedure.